K062660

4925 Coye Drive
Suite D
Stevens Point, WI 54481
715-254-0991
715-254-0996 (fax)
dhmunsey@kimobility.com

OCT 2 4 2006

October 13, 2006

510(k) Summary of Safety and Effectiveness

Submitter

Ki Mobility
4925 Coye Drive
Suite D
Stevens Point, WI 54481
USA

Telephone: (715) 254-0991
Fax: (715) 254-0996

Contact: Douglas H. Munsey

510(k) Number: K062660

Trade Name: Catalyst

Common Name: Folding Ultra-Lightweight Manual Wheelchair

Classification Name: Mechanical wheelchair

Classification: Class I

Predicate Device

The predicate device is the Quickie 2 wheelchair. K850536

Device Description

The Catalyst is a traditional folding cross-brace wheelchair. It is made of lightweight aluminum tubing similar to what is used on existing products. The frame utilizes two cross tube sets and, when opened, nestles inside of the frame onto 4 hooks to create a box like rigid assembly. Upon the outside of this framework, and to the rear, are assembled 2 machined aluminum axle plates. Stainless steel receivers are mounted within the axle plates. Wheels of varying size and type are connected to the receivers via stainless steel axles.

On the front end of the frame are assembled 2 aluminum housings. Caster forks are mounted to these housings via stainless steel axles. A variety of caster wheels and tires are then connected to the forks.

Upon the top of the frame is attached a seat sling. Into the rear of the frame assembly 2 backtubes are inserted to the desired height. Backrest upholstery is affixed to the backtubes.

Armrests receivers bolt onto the rear of each side frame. Individual Swing Away tubular arms are then inserted into the receivers. If flipback armrests are chosen a receiver is mounted onto the from of each side frame to catch the forward most section of the arm and the rear mounting is pivoting to allow the arm to rotate backward. Height Adjustable arms fit into a receiver that mounts onto the outside of the frame.

Wheel locks mount onto the upper side frame and are adjusted so that the brake arm engages with the tire and when in the locked position prevents to the wheel from rotating.

Swing Away footrests with footplates and heel loops attach at the front of the chair. There is a plug at the top of the footrest hanger that inserts into an opening at the top front of the wheelchair frame. The footrest hanger is turned 90 degrees away from the frame. Hold the latch, which is midway down the hanger, tightly against the front of the frame and rotate the footrest back towards center. The latch will engage once the footrest hanger is centered.

Feature	Description	Materials
Intended Use	The Catalyst wheelchair is a manually operated device intended to be used as a means of mobility for persons restricted to a sitting position.	
Primary Frame Materials	6061-T6 Aluminum	6061-T6 Aluminum
Folding Method	Collapsible Cross-brace	6061-T6 Aluminum
Frame Widths	14" to 20"	
Overall Width	20.5" to 26.5"	
Seat Depths	14" to 20"	
Back Heights	8.5" to 19"	
Weight Limit	220 lbs	
Seat Height	15" to 21"	
Chair Weight	23 lbs (w/o footrests)	
Warranty	Lifetime on frame	
Armrests	1. Flip Back Height Adjustable – Desk & Full Length Arm pads 2. Flip Back Desk & Full Length Arm pads 3. Height Adjustable– Desk & Full Length Arm pads 4. Tubular Swing-Away	1,2,3 - 6061-T6 Aluminum tubing, ERW 1020 Steel upper, plastic side guard, 303 stainless steel pin, Plastic armrest pad 4. - 6061-T6 Aluminum
Front End Type	Swing-Away, Non-Swing Away	Welded 6061-T6 Aluminum
Back Type	Straight with push handles, 8 degree bend with push handles, no push handles	6061-T6 Aluminum
Footrests Hangers	70°, Elevating legrest	Welded 6061-T6 Aluminum
Footplates	Composite, Foam, Angle Adjustable	Composite - Nylon 66 with 15% short glass. Foam - 6061-T6 Aluminum with PU foam cover Angle Adj - 6061-T6 Aluminum plate
Extension Tubes	Ex. Short, Short, Medium, Long	6061-T6 Aluminum
Back Heights	8.5" to 19" in 3 adjustable sections	

Back Upholstery	Sewn Nylon Parapak 420D w/ ¾" polyurethane foam batting	Sewn Nylon Parapak 420D w/ ¾" polyurethane foam batting
Seat Upholstery	Sewn Dacron Polyester Sailcloth – No filling	Sewn Dacron Polyester Sailcloth – No filling
Cushion	2' foam cushion	Manufactured and distributed by Hudson Industries. Model - ***Pressure Eez 2 General Seat Cushion***
Axle Plates	Standard, Curved, Amputee, Offset	Machined 6061-T6 Aluminum
Axle	Quick Release or Fixed	Machined 303 Stainless steel
Wheel Sizes	22,24,26	
Wheel Types	Spoke, Composite Mag, Octopus (performance spoke)	Spoke & Octopus- Machined 6061-T6 Aluminum rims, Stainless steel spokes, Machined 6061 – T6 Aluminum hub Mag – Nylon 66 with 15% short Glass
Tire Types	Pneumatic, Pneumatic w/ airless insert, Full profile Polyurethane, Low Profile Polyurethane, Iron Cap (puncture resistant), High Pressure	Synthetic rubber and Urethane
Handrims	Aluminum, Plastic Coated, Projections	6061-T6 Aluminum, anodized or covered with PVC coating
Caster Sizes	4", 5", 6", 7", 8"	
Caster Types	Poly, Pneumatic, Pneumatic w/ airless insert	Nylon 66 with 15-30% short glass. Synthetic rubber and Urethane tires
Forks Sizes	4", 5", 6", 7"	Machined 6061-T6 Aluminum
Fork Stem Sizes	Std, +3/4", +1 ½"	Machined 303 Stainless steel
Wheel Locks	Push to Lock, Pull To Lock, Scissor Lock	Machined 6061-T6 Aluminum
Anti Tips Tubes	Locate off of the axle to insure safety at all seat heights	Cast aluminum housing with 6061-T6 tubes and plastic wheels
Where used	Solid surface	
Target Population	Persons restricted to a sitting position.	
Standards	Static Stability and Fatigue Strength: ANSI/RESNA Wheelchair Std. Vol. 1 Sections 1, 5, 7, 8, 16 & 93	
Tubing wall thicknesses	.070" on frame except front vertical tube, which is .1". X-tube is .070.	
Tube properties	6061-T4 prior to welding. After welding the component is heat treated up to T-6.	

Indications for Use

The Catalyst wheelchair is a manually operated device intended to be used as a means of mobility for persons restricted to a sitting position.

Technological Comparison to the Predicate Device

Feature	Quickie 2	Catalyst
Intended Use	The Quickie wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.	The Catalyst wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.
Primary Materials	6061-T6 Aluminum	6061-T6 Aluminum
Folding Method	Collapsible Cross-brace	Collapsible Cross-brace
Frame Widths	11" to 22"	14" to 20"
Overall Width	20.5" to 28.5"	20.5" to 26.5"

Seat Depths	10" to 20"	14" to 20"
Back Heights	8.5" to 19"	8.5" to 19"
Weight Limit	250 lbs (350lbs. Heavy Duty)	220 lbs
Seat Height	16.75" to 22.75"	15" to 21"
Chair Weight	27 lbs (w/o footrests)	23 lbs (w/o footrests)
Warranty	Lifetime on frame	Lifetime on frame
Armrests	1. Flip Back Height Adjustable – Desk & Full Length Arm pads 2. Flip Back 3. Height Adjustable– Desk & Full Length Arm pads 4. Tubular Swing-Away 5. Adjustable Locking Flip-up 6. Length Adjustable Locking Flip-up	5. Flip Back Height Adjustable – Desk & Full Length Arm pads 6. Flip Back Desk & Full Length Arm pads 7. Height Adjustable– Desk & Full Length Arm pads 8. Tubular Swing-Away
Front End Type	Swing-Away, Non-Swing Away	Swing-Away, Non-Swing Away
Back Type	Std, Angle Adjustable, Depth Adjustable	Std
Footrests Hangers	60°, 70°, 70°V, 90°, Articulating Legrest, Elevating legrest, 90° Elevating, 1-Piece	70°, Elevating legrest
Footplates	Composite, Foam, Aluminum, Angle Adjustable, Platform Flip-up, Locking Angle Adjustable	Composite, Foam, Angle Adjustable
Extension Tubes	Ex Short, Short, Medium, Long	Ex Short, Short, Medium, Long
Back Upholstery	Low, Medium, Tall, Adjustable, Reinforced	Low, Medium, Tall, Adjustable
Axle Plates	Standard, Curved, Amputee, Offset	Standard, Curved, Amputee, Offset
Wheel Sizes	20,22,24,26	22,24,26
Wheel Types	Spoke, Composite Mag, Spinergy (performance spoke), One Arm Drive	Spoke, Composite Mag, Octopus (performance spoke)
Tire Types	Pneumatic, Pneumatic w/ airless insert, Full profile Polyurethane, Low Profile Polyurethane, Kevlar (puncture resistant), High Pressure	Pneumatic, Pneumatic w/ airless insert, Full profile Polyurethane, Low Profile Polyurethane, Iron Cap (puncture resistant), High Pressure
Handrims	Aluminum, Plastic Coated, Projections	Aluminum, Plastic Coated, Projections
Caster Sizes	4", 5", 6", 8", 8x2	4", 5", 6", 8"
Caster Types	Poly, Semi-Pneumatic, Soft Roll, Pneumatic, Pneumatic w/ airless insert	Poly, Pneumatic, Pneumatic w/ airless insert
Forks Sizes	3", 4", 5 ¼", 6", 7", Frog Legs	4", 5", 6", 7", Frog Legs
Fork Stem Sizes	Std, +3/4", +1 ½"	Std, +3/4", +1 ½"
Caster Options	Multi-Position Fork, Caster Pin Locks, Quick Release Caster Stems	NA
Wheel Locks	Push to Lock, Pull To Lock, Scissor Lock, Grade Aid	Push to Lock, Pull To Lock, Low Profile
Anti Tips Tubes	Yes	Yes
Power Adapter	Quickie Extender	NA
Where used	Solid surface.	Solid surface
Target Population	Persons restricted to a sitting position.	Persons restricted to a sitting position.
Standards	Unknown	Static Stability and Fatigue Strength: ANSI/RESNA Wheelchair Std. Vol. 1 Sections 1, 5, 7, 8, 16 & 93
Tubing wall thicknesses	.083" on frame except front vertical tube, which is .125". X-tube is variable in thickness from .083" to .125" as it is a custom extrusion	.070" on frame except front vertical tube, which is .1". X-tube is .070.
Tube properties	6061 – T6 prior to welding. Hardness	6061-T4 prior to welding. After welding

	reduced to between T0 and T2 after welding.	the component is heat treated up to T-6.

It is Ki Mobility's conclusion that the Catalyst manual wheelchair is substantially equivalent to the Quickie 2 manual wheelchair currently marketed by Sunrise Medical.

Summary of Performance Testing

The Catalyst has been tested and found to comply with the ANSI-RESNA WC Volume 1 1998 standards sections 1, 5, 7, 8, 16 & 93.

Conclusions

As stated above, Ki Mobility's conclusion is that the Catalyst wheelchair is safe, effective, complies with the appropriate medical device standards, and is substantially equivalent to the Quickie 2 wheelchair.

This *510(k) Summary of Safety and Effectiveness* may be copied and submitted to interested parties as required by 21CFR807.92.

STANDARD	TITLE and COMMENTS
ANSI-RESNA WC - Vol 1 –1998 Section 1	Determination of static stability
ANSI-RESNA WC - Vol 1 –1998 Section 8	Static, impact, and fatigue strengths
ANSI-RESNA WC- Vol 1 – 1998 Section 16	Determination of Flammability
ANSI-RESNA WC - Volume 1-1998 Section 5	Determination of Overall Dimensions, Mass and Turning Space
ANSI-RESNA WC - Volume 1-1998 Section 7	Measurement of seating and wheel dimensions
ANSI-RESNA WC - Volume 1-1998 Section 93	Maximum Overall Dimension

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ki Mobility LLC
% Mr. Douglas H. Munsey
4925 Coye Drive, Suite D
Stevens Point, Wisconsin 54481

OCT 2 4 2006

Re: K062660
Trade/Device Name: Catalyst
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: October 6, 2006
Received: October 10, 2006

Dear Mr. Munsey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant:
Ki Mobility
4925 Coye Drive
Suite D
Stevens Point, WI 54481
USA

Telephone: (715) 343-1280
Fax: (715) 343-1280
510(k) Number: K062660

Device Name: Catalyst

Indications for Use:
The Catalyst wheelchair is a manually operated device intended to be used as a means of mobility for persons restricted to a sitting position.

Prescription Use_____ OR Over-The-Counter _____X_____
(Per 21 CFR 801.116)

(Please do not write below this line – continue on another page if needed)

Barbara Pruchno

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of General, Restorative, and Neurological Devices

510(k) Number K062660